



National Environmental
Laboratory **Accreditation**
Conference

Accrediting Authority

Proposed Changes

January 12, 1998

6.2 GENERAL PROVISIONS

. . . .

- g) Accrediting authorities are encouraged to establish one or more technical committees for advising the accrediting authority on the technical matters relating to the operation of its environmental laboratory

. . . .

- 2) a structure where committee members are chosen to provide relevant competent technical support and impartiality through a balance of interests where no single interest predominates.

6.2.1 Reciprocity

. . . .

- e) If a NELAP-recognized secondary accrediting authority notes any potential nonconformance with the NELAC standards by a laboratory during the initial application process for reciprocal accreditation, or for a laboratory that ~~it has already~~ has been granted NELAP accreditation through reciprocity, the NELAP-recognized secondary accrediting authority shall immediately notify, in writing, the applicable NELAP-recognized primary accrediting authority and the laboratory. However, the laboratory is to be notified only in situations where no administrative or judicial prosecution is contemplated. The notification must cite the applicable sections within the NELAC standards for which nonconformance by the laboratory has been noted.

. . . .

- f) Upon receipt of the subsection 6.2.1(e) notification, the NELAP-recognized primary

6.2.2 Where to Apply for NELAP Accreditation

. . . .

- b) Except for governmental laboratories ~~in federal departments or agencies holding NELAP recognition as an accrediting authority~~ noted in subsection 6.2.2(e)

below, all laboratories seeking NELAP accreditation or renewal of NELAP accreditation must apply for such accreditation through their home state (the state in which the laboratory facility is located) accrediting authority.

c) Laboratories located in a territory or other state that is not NELAP-recognized may seek NELAP accreditation through any NELAP-recognized accrediting authority.

~~d) Governmental laboratories not an organizational unit within the department or agency in which the accrediting authority is located shall apply for NELAP accreditation through their home-state accrediting authority.~~

d) RESERVED

e) Governmental laboratories that are organizational units of the same department or agency in which the accrediting authority is located or have other institutional conflicts of interest ~~may~~ shall:

1) demonstrate by organizational structure that the laboratory's responsible party of record and the environmental laboratory accreditation program manager do not report ~~to~~ within the same individual chain-of-command; and

. . . .

6.2.3 Documentation Maintained by Accrediting Authorities

. . . .

b) When the document or documents reviewed in subsection 6.2.3(a)(2) above reveals

c) The document or documents described in subsection 6.2.3(a)(1) above shall be

6.3.1 Written Application for NELAP Recognition

. . . .

- b) The application shall request information that is essential for the NELAP to evaluate
- 3) the policies, guidance documents, promulgating instructions and standard operating procedures governing the operation of the accrediting authority's environmental laboratory accreditation program as set forth in subsection 6.3.3.1 ;
- 4) the accrediting authority's arrangements for liability insurance and workman's compensation ~~insurance~~ assurance coverage as required in subsection 6.3.3.1 (d);

6.3.2 Application Completeness Review by NELAP

. . . .

- c) Following receipt of an initial or a renewal application, the NELAP must complete a review of the
- 3) The accrediting authority must provide any additional information or clarification requested in writing within ten days of receipt of the 6.3.2(c)(2) notification.

. . . .

6.3.3.1 Required Technical Elements of a NELAP-Recognized Accrediting Authority's Program

. . . .

- c) The accrediting authority shall have the authority, rights and responsibilities necessary to carry out an environmental laboratory accreditation program;

. . . .

- m) The accrediting authority shall require NELAP-accredited laboratories to participate in a proficiency testing program meeting the requirements of the NELAC standards, Chapter two, Proficiency Testing.

6.3.3.1.3 Accrediting Authority's Quality System

.

- b) The quality system shall be documented in a quality manual and associated written quality procedures- and shall be made available for use by the staff. The quality manual shall include at least the following:

.

- 3) the procedures for acquiring, training, supervising and evaluating
- 5) the system for providing feedback to personnel responsible for the area audited and for taking timely and appropriate corrective actions whenever discrepancies are detected; ~~and~~

.

- 7) the procedures established to maintain document control for documents required by the NELAC standards-i
- 8) the procedures and policies to implement the accreditation process; and
- 9) the procedures and policies for dealing with appeals, complaints and disputes by laboratories.

6.3.3.2 Application Technical Review Report

- a) The NELAP assessment team will accept an initial application and its supporting documentation for continued processing that contains sufficient information
- b) The NELAP assessment team will accept a renewal application and its supporting documentation for continued processing that contains sufficient information
- c) Except as noted in Section 6.5, the NELAP assessment team will not accept the application for continued processing if it notes deficiencies.
- d) ~~The~~ To proceed with the review process, the accrediting authority shall respond with written corrective actions

within 30 days of receipt of the NELAP assessment team's subsection 6.3.3.2(c) notification. The NELAP assessment team

. . . .

- 3) If application deficiencies still remain after the assessment team's second attempt to resolve those deficiencies, the NELAP assessment team will document those deficiencies which are not resolved and recommend
- e) If the initial application as submitted contained no deficiencies or if deficiencies were corrected as provided in subsection 6.3.3.2(d), except those deficiencies requiring legislative or rulemaking action as set forth in Section 6.5, the NELAP assessment team will schedule the on-site audit as set forth in subsection 6.4.1 below.

. . . .

6.3.4 Notification of Changes to An Accrediting Authority's Program

- a) For all changes in the accrediting authority's environmental laboratory accreditation program listed below, the NELAP Director shall be notified of changes to:
 - 1) the authority to accredit laboratories as stated in the statutes ~~and~~, regulations and promulgating instructions establishing and governing the accrediting authority's environmental laboratory accreditation program,
 - 2) the organizational structure ~~involving either the management or technical staff,~~

. . . .

6.4 ON-SITE AUDIT OF THE ACCREDITING AUTHORITY

. . . .

- b) The NELAP assessment team will arrange on-site audits except as stated in subsection 6.4(c) below at the mutual convenience of the parties.

6.4.3 On-Site Audit Reports

. . . .

- e) The NELAP assessment team shall recommend to the NELAP Director revocation or denial of NELAP recognition for on-site audit deficiencies for any accrediting authority that fails to submit a plan of corrective action within 30 days as set forth in subsection 6.4.3(d) above.

. . . .

- g) The NELAP assessment team shall review the corrective actions for the remaining deficiencies within 15 days of receipt of a subsection 6.4.3(f)(2) response from the accrediting authority.

. . . .

6.7 CERTIFICATE OF RECOGNITION TO THE ACCREDITING AUTHORITY

. . . .

- b) The certificate of NELAP recognition shall include the following items:

. . . .

- 8) a statement that continued NELAP recognition depends on compliance with the NELAC standards;
~~and~~
- 9) a seal incorporating the NELAP insignia~~;~~i and
- 10) a unique designator, such as date of issuance and a serial or certificate number.

. . . .

6.9.1 NELAP Assessment Team

.

e) The NELAP assessment team shall:

.

2) have at least one member with experience that includes at least one of the following:

A) registration as a lead assessor as set forth in the most recent editions of:

i. ISO Guide 10011, Guidelines for Auditing Quality Systems Part 1, "Auditing",

ii. ISO Guide 10011, Part 2, "Management of Audit Programmes",

iii. The National Association of Testing Authorities (NATA), Topic 11, Appendix A "Qualifications and Experience For Quality Systems Assessors", and

iv. NATA, Topic 11, Appendix B "Qualifications and Experience For Quality Systems Lead Assessors";